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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/866,826 | 05/30/2001 | John F. Currie | SAIC0045-US | 5090 |
| 27510 | 7590 | 03/22/2004 | EXAMINER | |
| KILPATRICK STOCKTON LLP 607 14TH STREET, N.W. SUITE 900 WASHINGTON, DC 20005 | | | KREMER, MATTHEW J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | <i>TS</i> |

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------|------------------------|---------------------|
| Advisory Action | Application No. | Applicant(s) |
| | 09/866,826 | CURRIE ET AL. |
| | Examiner | Art Unit |
| | Matthew J Kremer | 3736 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) The period for reply expires 3 months from the mailing date of the final rejection.
 b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
 ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will not be entered because:
 - (a) they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) they raise the issue of new matter (see Note below);
 - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see Attached.

3. Applicant's reply has overcome the following rejection(s): _____.
4. Newly proposed or amended claim(s) 95-104 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8. The drawing correction filed on ____ is a) approved or b) disapproved by the Examiner.

9. Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

10. Other: _____.

ADVISORY ACTION

Response to Arguments

In regard to claims 1 and 26, the Applicant contends that Berner et al. does not teach or suggest of assembling a microfabricated device with all the functionality of the claims device. The Examiner respectfully disagrees. Berner et al. teaches that a selection of sampling devices can be used including WO 97/42882 to Mercury Diagnostics. This sampling device includes the use of a microfabricated assembly because it uses capillary tubes, microporous test strips (page 6, line 15 to page 7, line 3 of Mercury), and injectors that introduce one micron to 10 mil diameter powder. (page 14, lines 19-35 of Mercury). It was this reference that the Examiner was referring on page 14 of the Final Rejection mailed on 12/29/2003. In other words, the Examiner was referencing column 5, line 60 to column 6, line 50 of Berner et al. not column 6, line 40 to column 6, line 60. Despite the typo by the Examiner, the Examiner did address the argument of the device having a microfabricated assembly and attempted to point to the specification, which taught such an assembly. Although the exact place in the specification was not pointed out, the general area was correct and the Applicant should have realized that since the claim limitation at issue was addressing the sampling device, the sampling device of Berner et al. was the item the Examiner was referring to and not the housing.

As to claims 16-17, 39-40, and 57, the receptacle contains a material which is ionically conductive (water with ions) (column 6, lines 8-25 of Berner et al.). This water

is considered to be a fluid positioned in the reservoir. In regard to claim 16, the language "for transmitting the fluid to a subject's skin to promote flow of said at least one analyte into said at least one conduit" is merely "intended use" language, which cannot be relied upon to define over Berner et al., since Berner et al. discloses all of the claimed elements and their recited relationships. See *Ex parte Masham* 2 USPQ 2nd 1647. In regard to claim 17, the language "capable of permeating a subject's skin" does not make the claim patentable of the prior art since water is capable of permeating the skin when used in hydraulic jets. (page 14, lines 19-35 of Mercury).

As to any arguments relating to claims 3-25 and 28-71, any reliance on the teaching that a microfabricated assembly is not disclosed is raising new issues that require further search and consideration in relation to those claims since the subsequent claims were not necessarily considering a microfabricated assembly as being part of the claimed subject matter in those claims. The use of the "microfabricated" in the preamble of these claims were not given patentable weight because the Examiner did not feel that such a preamble breathed life into the claim since no structure in the claims were limited to being microfabricated. This is supported by the fact that some dependant claims referred to the microfabricated assemblies in the body of the claims so it follows that such microfabricated assemblies were not part of the independent claims. The Applicant has noted that the "independent claims of the pending application have been amended to overcome the rejection over Berner" (page 22 of Amendment and Response to Final Office Action filed on 3/11/2004) which reinforced that fact that new issues are raised and further consideration is required.

As to the arguments that the teachings of Sepaniak et al. do not overcome the supposed deficiencies of Berner, the rejection of the claims in view of the Berner/Sepaniak combination are maintained because the rejections of the claims in view of Berner are deemed proper due to the reasons stated above.

As to claim 95, that rejection has been withdrawn because the Examiner agrees that Sepaniak does not teach that the an analyte displaces by competitive binding a fluorophore from the specific-binding molecule and that subsequent fluorescence from the displaced fluorophore correlates with the amount of analyte present.

The Examiner has noted that the Applicant has attempted to amend claims 96-104 to depend from claim 95 rather than claim 94. Such an amendment would cause the Examiner to withdraw the rejections in view of the Berner/Sepaniak combination, the proposed amended claims 96-104 would be allowable if the proposed amendments were submitted in a separate, timely filed amendment canceling the non-allowable claims.

As to the arguments that the teachings of Shehada do not overcome the supposed deficiencies of Berner or Sepaniak, the rejection of the claims in view of the Berner/Sepaniak/Shehada combination are maintained because the rejections of the claims in view of Berner and Sepaniak are deemed proper due to the reasons stated above.

As to claims 19, 21-22, 42, 87-89, and 58, in regard to the Applicant's assertion the Eppstein does not teach that the pump 21 pumps fluid into contract with the skin of a subject, it is noted that the limitation "for pumping said fluid into contract with the skin of a subject" is merely "intended use" language, which cannot be relied upon to define over the combination, since the combination discloses all of the claimed elements and their recited relationships. See *Ex parte Masham* 2 USPQ 2nd 1647. Claim 21 merely requires a pump and the hydraulic jet of the combination includes a pump for pumping fluid (water) to promote flow, which is what micro-poration does.

As to the arguments that the teachings of Conn do not overcome the supposed deficiencies of Berner, the rejection of the claims in view of the Berner/Conn

combination are maintained because the rejections of the claims in view of Berner are deemed proper due to the reasons stated above.

As to the arguments that the teachings of Sepaniak do not overcome the supposed deficiencies of Berner or Conn, the rejection of the claims in view of the Berner/Conn/Sepaniak combination are maintained because the rejections of the claims in view of Berner/Conn combination are deemed proper due to the reasons stated above.

As to the arguments that the teachings of Shehada do not overcome the supposed deficiencies of Berner or Conn or Sepaniak, the rejection of the claims in view of the Berner/Conn/Sepaniak/Shehada combination are maintained because the rejections of the claims in view of Berner/Conn/Sepaniak combination are deemed proper due to the reasons stated above.

In regard to claim 115, the introduction of new claims after the Final Rejection raises new issues that were not considered and would required new consideration and further searching.

As to claim 18, in response to applicant's argument that the Berner/Bremer combination fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the seal is to break during normal operation) are not recited in the rejected claim(s). The claim merely recites a breakable seal and the combination teaches a peelable seal and anything is breakable with sufficient force exerted on it. As the Examiner has already addressed this argument in the Final Rejection, the Final Rejection is properly maintained.

As to the arguments that the teachings of Ishikawa do not overcome the supposed deficiencies of Berner or Bremer, the rejection of the claims in view of the Berner/Bremer/Ishikawa combination are maintained because the rejections of the claims in view of Berner/Bremer combination are deemed proper due to the reasons stated above.

As to the arguments that the teachings of Montecalvo do not overcome the supposed deficiencies of Berne or Eppstein, the rejection of the claims in view of the Berner/Eppstein/Montecalvo combination are maintained because the rejections of the claims in view of Berner/Eppstein combination are deemed proper due to the reasons stated above.

*Mary Bolger
Art. Unit 3736
Art. Unit 3751*